

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the amendments above and the comments below.

Claims 51-62, 73-75 and 154 are pending in the subject application. The claims have been amended to more particularly define the antibody fragment as a fragment of the monoclonal antibody and to define the Fas ligand that is detected by the antibody or fragment as a human or mouse Fas ligand. Support for the latter amendment is found at page 56, lines 17-19, which disclose detection of the human Fas ligand expressed on L5178Y cells, and the paragraph bridging pages 13 and 14, which discloses detection of the mouse Fas ligand of cells derived from both B6 and C3H mice. Claim 51 was amended to define which particular monoclonal antibodies detect human Fas ligand and which detects mouse Fas ligand. Claim 74 was amended to correct a typographical error.

The amendments to the claims do not add new matter, and merely serve to more particularly define the claimed invention in terms of the source of Fas ligand detected by the claimed antibody. It is respectfully submitted that these amendments place the application in condition for allowance and therefore, should be entered.

I. Rejection of Claims 51, 53-63, 73-75 and 154 Under 35 U.S.C. § 112, First Paragraph

Claims 51, 53-63, 73-75 and 154 stand rejected under 35 U.S.C. § 112, first paragraph. The Examiner states that specific hybridomas are essential to making and using the claimed invention and therefore, must be deposited under the terms of the Budapest Treaty. The Examiner also states that the specification does not teach how to use any monoclonal antibody or any active fragment of the claimed monoclonal antibody that specifically reacts with any Fas ligand. The

Examiner also asserts that description of human fas ligands is essential to practicing the claimed invention.

This rejection is respectfully traversed as follows.

Enclosed herewith are the deposit receipts of the hybromas that produce the claimed antibodies. Applicant agrees that all restrictions imposed by the depositor on the availability to the public of the deposited materials will be irrevocably removed upon the granting of a patent throughout the life of the patent.

The claimed invention is directed to monoclonal antibodies produced by one of five specified hybridoma cell lines that are described in detail in the specification and are deposited in a recognized cell depository under the terms of the Budapest Treaty, as well as active fragments thereof selected from F9ab')₂, Fab', Fab, Fv or recombinant Fv. As set forth in the claims, the monoclonal antibody or fragment thereof specifically reacts with human Fas ligand and inhibits apoptosis at a specified concentration, or reacts specifically with mouse Fas ligands of the B6 and C3H strains. Binding to a human or mouse Fas ligand is an inherent property of the claimed monoclonal antibodies and has been amply demonstrated in the specification. Moreover, the specification teaches in great detail at pages 37-44 the identity of several active fragments of the monoclonal antibodies.

It is not necessary to know the structure, *e.g.* sequence of a Fas ligand in order to practice the claimed invention. That the claimed monoclonal antibodies and active fragments recognize human or mouse Fas ligands is an inherent property of the monoclonal antibody. Moreover, the Fas ligand is well known in the art by its function, which is sufficient for one of skill in the art to recognize the molecule.

Accordingly, the rejection of the claims under 35 U.S.C. § 112, first paragraph is respectfully traversed.

II. Rejection of Claims 73-75 and 154 Under 35 U.S.C. § 112, First Paragraph

Claims 73-75 and 154 stand rejected under 35 U.S.C. § 112, first paragraph. The Examiner states that the claims contain subject matter that was not described in the specification in such a way as to convey to one of skill in the art that the inventor had possession of the claimed invention at the time of filing.

Applicant respectfully disagrees with the examiner.

The specification teaches methods of making monoclonal antibodies using specified Fas expressing cells. Both human and mouse Fas expressing cells were used and in each case, monoclonal antibodies were produced that react with the appropriate Fas ligand. The claimed method is not limited to a particular hybridoma or a use of a particular Fas-expressing cell line because Applicant's studies have shown that any cells expressing Fas can be used to generate hybridomas that produce monoclonal antibodies that react with Fas.

As noted above, the skilled practitioner knows the structure and function of Fas ligands and therefore, knows how to identify the molecule. Knowledge of the specific sequence of the Fas molecule is not necessary to practice the claimed invention. One of ordinary skill in the art can identify other Fas expressing cells or Fas ligands without undue experimentation. Thus, the specification, which teaches in detail the method of claims 73-75 and 154 provides sufficient written description of the claimed invention.

Accordingly, the rejection of claims 73-75 and 154 under 35 U.S.C. § 112, first paragraph, is respectfully traversed.

III. Rejection of Claims 73-75 Under 35 U.S.C. § 103(a)

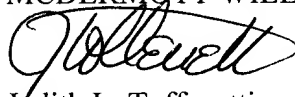
It is respectfully submitted that the amendment to claim 73 renders the rejection of these claims as obvious over the cited prior art moot. Specifically, the amended claims recite six specified hybridoma that produce the claimed monoclonal antibodies. Since these hybridomas are not known in the art and monoclonal antibodies having the claimed properties are neither known, nor obvious in view of the prior art, the rejection is respectfully traversed.

It is respectfully submitted that the present application, as amended above, is in condition for allowance, an early notification thereof being earnestly solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

MCDERMOTT WILL & EMERY LLP



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Date: September 27, 2004



INTERNATIONAL FORM

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF
MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITARY AUTHORITY
identified at the bottom of this page.

Depositor:

Name: SUMITOMO ELECTRIC INDUSTRIES, LTD.
Noritaka Kurauchi, Esq.
President

Address: Postal Code: 541
5-33, Kitahama 4-chome, Chuo-ku, Osaka-shi, Osaka

I . Indication of Microorganisms	
(Indication for Identification Given by Depositor) NOK1	(Deposition No.) FERM BP- 5044
II . Scientific Nature and Taxonomic Position	
A document in which the following facts were described has been attached to the microorganisms set forth in Row I. <input checked="" type="checkbox"/> Scientific Nature <input checked="" type="checkbox"/> Taxonomic Position	
III . Acceptance and Receipt	
This international depository authority receives the microorganisms set forth in Row I accepted on March 20, 1995 (original depositing date).	
IV . Acceptance of request for transfer of jurisdiction	
This international depository authority accepted the microorganisms set forth in Row I on (original depositing date), and accepted a request for transfer of jurisdiction from the original deposit to a deposit based on Budapest Treaty on	
V . International depository authority	
Name: National Institute of Bioscience and Human-Technology, Agency of Industrial Science and Technology Osamu Suzuki, Dr., DIRECTOR GENERAL.	
Address: 1-3, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken 305, Japan	
Date: March 20, 1995	

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I . Indication of Microorganisms	
(Indication for Identification Given by Depositor) NOK3	(Deposition No.) FERM BP- 5046
II . Scientific Nature and Taxonomic Position	
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II . Scientific Nature and Taxonomic Position	
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I . Indication of Microorganisms	
(Indication for Identification Given by Depositor) NOK5	(Deposition No.) FERM BP- 5048
II . Scientific Nature and Taxonomic Position	
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I . Indication of Microorganisms	
(Indication for Identification Given by Depositor) KAY-10	(Deposition No.) FERM BP- 5334
II . Scientific Nature and Taxonomic Position	
A document in which the following facts were described has been attached to the microorganisms set forth in Row I. <input checked="" type="checkbox"/> Scientific Nature <input checked="" type="checkbox"/> Taxonomic Position	
III . Acceptance and Receipt	
This international depository authority receives the microorganisms set forth in Row I accepted on December 14, 1995 (original depositing date).	
IV . Acceptance of request for transfer of jurisdiction	
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V . International depository authority	
Name: National Institute of Bioscience and Human-Technology, Agency of Industrial Science and Technology Osamu Suzuki, Dr., DIRECTOR GENERAL.	
Address: 1-3, Higashi 1-chome, Tsukuba-shi, Ibaraki-ken 305, Japan	
Date: December 14, 1995	



〔 特許手続上の微生物の寄託の国際的承認
に関するブダペスト条約 〕

下記国際寄託当局によって規則 7. 1 に従い
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BUDAPEST TREATY ON THE INTERNATIONAL
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氏名 (名称) 住友電気工業株式会社
代表取締役 倉内 憲孝
寄託者 あて名 ⑤ 541 殿
大阪府大阪市中央区北浜四丁目 5 番 3 3 号

I. 微生物の表示

(寄託者が付した識別のための表示)
NOK1

(受託番号)
FERM BP- 5044

II. 科学的性質及び分類学上の位置

I 欄の微生物には、次の事項を記載した文書が添付されていた。

- ☒ 科学的性質
☒ 分類学上の位置

III. 受領及び受託

本国際寄託当局は、平成 7 年 3 月 20 日 (原寄託日) に受領した I 欄の微生物を受託する。

IV. 移管請求の受領

本国際寄託当局は、年 月 日 (原寄託日) に I 欄の微生物を受領した。
そして、年 月 日に原寄託よりブダペスト条約に基づく寄託への移管請求を受領した。

V. 国際寄託当局

通商産業省工業技術院生命工学工業技術研究所

名称: National Institute of Bioscience and Human-Technology
Agency of Industrial Science and Technology

所長 鈴木 修 Osamu Suzuki, DIRECTOR GENERAL.

あて名: 日本国茨城県 1 丁目 1 番 3 号 (郵便番号 305)
1-3, Higashi 1 chome Tsukuba-shi Ibaraki-ken
305, JAPAN

平成 7 年 (1995) 3 月 20 日



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代表取締役 倉内 憲孝
寄託者 あて名 ⑤ 541 殿
大阪府大阪市中央区北浜四丁目 5 番 3 3 号

I. 微生物の表示

(寄託者が付した識別のための表示)
NOK2

(受託番号)
FERM BP- 5045

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名称: National Institute of Advanced Industrial Science and Human-Technology
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所長 鈴木 修
Osamu Suzuki, DIRECTOR GENERAL.

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寄託者 あて名 ⑤ 541 殿
大阪府大阪市中央区北浜四丁目 5 番 3 3 号

I. 微生物の表示

(寄託者が付した識別のための表示)
NOK3

(受託番号)
FERM BP- 5046

II. 科学的性質及び分類学上の位置

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寄託者 あて名 ㊦ 541 殿
大阪府大阪市中央区北浜四丁目 5 番 3 3 号

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(寄託者が付した識別のための表示)
NOK5

(受託番号)
FERM BP- 5048

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BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF
MICROORGANISMS FOR THE PURPOSES OF
PATENT PROCEDURE

RECEIPT IN THE CASE OF AN ORIGINAL
DEPOSIT

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I. 微生物の表示

(寄託者が付した識別のための表示)
KAY-10

(受託番号)
FERM BP- 5334

II. 科学的性質及び分類学上の位置

I 欄の微生物には、次の事項を記載した文書が添付されていた。

- ☒ 科学的性質
☒ 分類学上の位置

III. 受領及び受託

本国際寄託当局は、平成 7 年 12 月 14 日 (原寄託日) に受領した I 欄の微生物を受託する。

IV. 移管請求の受領

本国際寄託当局は、
そして、 年 月 日 (原寄託日) に I 欄の微生物を受領した。
日に原寄託よりブダペスト条約に基づく寄託への移管請求を受領した。

V. 国際寄託当局

通商産業省工業技術院生命工学工業技術研究所

名称: National Institute of Science and Human-Technology
Agency of Science and Technology

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平成 7 年 (1995) 12 月 14 日

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